

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION**

NORMA NICELY,)	
)	
Plaintiff,)	
)	
v.)	CASE NO.: 4:11-CV-00338-NAB
)	
WYETH, et al.,)	
)	JURY TRIAL DEMANDED
Defendants.)	
)	
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**DEFENDANT PLIVA, INC.'S ANSWER, DEFENSES, AND JURY DEMAND
TO PLAINTIFF'S AMENDED PETITION**

Defendant PLIVA, Inc. ("PLIVA") hereby answers plaintiff's Amended Petition as follows:

I. INTRODUCTION

1. PLIVA denies the allegations in paragraph 1 of the Amended Petition directed to it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 1 of the Amended Petition directed to other defendants.

II. PARTIES

2. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 2 of the Amended Petition.

3. PLIVA admits that plaintiff refers to Ms. Nicely as the "Plaintiff" but is without knowledge or information sufficient to form a belief as to whether such reference is proper.

4. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 4 of the Amended Petition.

5. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 5 of the Amended Petition.

6. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 6 of the Amended Petition.

7. PLIVA admits that plaintiff collectively refers to Wyeth, Inc. d/b/a Wyeth, LLC and Wyeth Pharmaceuticals as “WYETH” but is without knowledge or information sufficient to form a belief as to whether such collective reference is proper. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 7 of the Amended Petition.

8. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 8 of the Amended Petition.

9. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 9 of the Amended Petition.

10. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 10 of the Amended Petition.

11. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 11 of the Amended Petition.

12. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 12 of the Amended Petition.

13. PLIVA admits that it has its principal place of business in New Jersey. Responding further, PLIVA states that Pliva, d.d. was a Croatian company headquartered in Zagreb, Croatia, but denies the remaining allegations in paragraph 13 of the Amended Petition.

14. PLIVA states that it was a wholly-owned subsidiary of Pliva, d.d. PLIVA denies the remaining allegations in paragraph 14 of the Amended Petition.

15. PLIVA denies the allegations in paragraph 15 of the Amended Petition.

16. PLIVA admits that Barr Pharmaceuticals, LLC (f/k/a Barr Pharmaceuticals, Inc.) (“Barr Pharmaceuticals”) is a Delaware corporation. PLIVA denies the remaining allegations in paragraph 16 of the Amended Petition.

17. PLIVA denies the allegations in paragraph 17 of the Amended Petition.

18. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 18 of the Amended Petition.

19. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 19 of the Amended Petition.

20. PLIVA states on December 23, 2008, Barr Pharmaceuticals, Inc., was merged with and into Boron Acquisition LLC, a privately-held, wholly-owned subsidiary of Teva Pharmaceuticals USA, Inc. The surviving company, Barr Pharmaceuticals, LLC is a privately-held, indirect wholly-owned subsidiary of Teva Pharmaceutical Industries Ltd., an Israeli company. PLIVA denies the remaining allegations in paragraph 20 of the Amended Petition.

21. PLIVA admits that plaintiff collectively refers to Barr Pharmaceuticals, LLC (f/k/a Barr Pharmaceuticals, Inc.), Pliva, Inc., and Teva Pharmaceuticals USA as “TEVA” but denies that such collective reference is proper.

22. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 22 of the Amended Petition.

23. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 23 of the Amended Petition.

24. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 24 of the Amended Petition.

25. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 25 of the Amended Petition.

26. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 26 of the Amended Petition.

27. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 27 of the Amended Petition.

28. PLIVA admits that plaintiff collectively refers to Wolters Kluwer US, Inc., Wolters Kluwer Health, and Facts and Comparison as “Wolters Kluwer” or “WK” but is without knowledge or information sufficient to form a belief as to whether such collective reference is proper. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 28 of the Amended Petition.

29. PLIVA admits that plaintiff collectively refers to Wyeth, Schwarz, and Alaven as the “Brand Defendants” but is without knowledge or information sufficient to form a belief as to whether such collective reference is proper. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 29 of the Amended Petition.

30. PLIVA admits that plaintiff collectively refers to Pliva, Barr, and Teva as the “Generic Defendants” but denies that such collective reference is proper. PLIVA admits that it has engaged in the manufacture, testing, sale, and distribution of generic metoclopramide, but that PLIVA never manufactured any metoclopramide product. PLIVA denies the remaining allegations in paragraph 30 of the Second Amended Complaint that are directed to it. PLIVA is

without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 30 of the Second Amended Complaint directed to other defendants.

31. PLIVA admits that plaintiff refers to Wolters Kluwer Health, Wolters Kluwer US, and Facts and Comparison as the “PEM Defendant” but is without knowledge or information sufficient to form a belief as to whether such collective reference is proper. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 31 of the Amended Petition.

32. PLIVA admits that plaintiff collectively refers to Wyeth, Schwarz, Alaven, Pliva, Barr, Teva, Wolters Kluwer Health, Wolters Kluwer US, and Facts and Comparison as the “Defendants” but denies that such collective reference is proper.

33. PLIVA denies the allegations in paragraph 33 of the Amended Petition directed to it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 33 of the Amended Petition directed to other defendants.

III. VENUE AND JURISDICTION

34. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 34 of the Amended Petition.

35. PLIVA denies the allegation in paragraph 35 of the Amended Petition.

36. PLIVA denies the allegations in paragraph 36 of the Amended Petition directed to it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 36 of the Amended Petition directed to other defendants.

37. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 37 of the Amended Petition.

38. PLIVA denies the allegations in paragraph 38 of the Amended Petition that are directed to it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 38 of the Amended Petition directed to other defendants.

39. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 39 of the Amended Petition.

40. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 40 of the Amended Petition.

41. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 41 of the Amended Petition.

42. PLIVA states that the allegation in paragraph 42 of the Amended Petition is an asserted conclusion of law to which re response is required. To the extent a response is required, PLIVA denies the allegations in paragraph 42 of the Amended Petition directed to it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 42 of the Amended Petition directed to other defendants.

IV. FACTS GIVING RISE TO PLAINTIFF'S CLAIMS

A. REGLAN/METOCLOPRAMIDE BACKGROUND

43. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 43 of the Amended Petition.

44. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 44 of the Amended Petition.

45. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 45 of the Amended Petition.

46. PLIVA admits that it has engaged in the manufacture and sale of generic metoclopramide. PLIVA denies the remaining allegations in paragraph 46 of the Amended Petition directed to it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 46 of the Amended Petition directed to other defendants.

47. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 47 of the Amended Petition directed to other defendants.

48. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 48 of the Amended Petition.

49. PLIVA states that metoclopramide is approved by the Food and Drug Administration (“FDA”) for the indications set forth in the FDA-approved package insert for Reglan. PLIVA denies that paragraph 49 of the Amended Petition completely or accurately characterizes the FDA-approved package insert for metoclopramide. PLIVA denies the remaining allegations in paragraph 49 of the Second Amended Petition.

50. PLIVA admits that metoclopramide has the pharmacological effects and properties set forth in its FDA-approved package insert. PLIVA denies the remaining allegations in paragraph 50 of the Amended Petition.

51. PLIVA admits that the indications and risks of metoclopramide are set forth in the FDA-approved package insert. PLIVA denies the remaining allegations in paragraph 51 of the Amended Petition.

52. PLIVA admits that the risks of metoclopramide are set forth in the FDA-approved package insert for Reglan. PLIVA denies that paragraph 52 of the Amended Petition

completely or accurately characterizes the FDA-approved package insert for metoclopramide. PLIVA denies the remaining allegations in paragraph 52 of the Amended Petition.

53. PLIVA states that the side effects of metoclopramide are set forth in the FDA-approved package insert for Reglan. PLIVA denies that paragraph 53 of the Second Amended Petition completely or accurately characterizes the FDA-approved package insert for metoclopramide. PLIVA denies the remaining allegations in paragraph 53 of the Amended Petition.

54. PLIVA states that the risks of metoclopramide are set forth in the FDA-approved package insert for Reglan. PLIVA denies that paragraph 54 of the Amended Petition completely or accurately characterizes the FDA-approved package insert for metoclopramide. PLIVA denies the remaining allegations in paragraph 54 of the Amended Petition.

55. PLIVA states that the risks of metoclopramide are set forth in the FDA-approved package insert for Reglan. PLIVA denies that paragraph 55 of the Second Amended Petition completely or accurately characterizes the FDA-approved package insert for metoclopramide. Further, PLIVA denies that paragraph 55 of the Second Amended Petition completely or accurately characterizes the symptoms of tardive dyskinesia, dystonia, and tremors. PLIVA denies the remaining allegations in paragraph 55 of the Second Amended Petition.

56. PLIVA denies that paragraph 56 of the Second Amended Petition completely or accurately characterizes the prognosis for patients diagnosed with tardive dyskinesia, dystonia, tremors, or akathisia. Further, PLIVA denies that paragraph 55 of the Second Amended Petition completely or accurately characterizes the symptoms of tardive dyskinesia, dystonia, and

tremors. PLIVA denies the remaining allegations in paragraph 56 of the Second Amended Petition.

57. PLIVA denies that paragraph 57 of the Second Amended Petition completely or accurately characterizes the prognosis for patients diagnosed with tardive dyskinesia, dystonia, tremors, or akathisia. PLIVA denies the remaining allegations in paragraph 57 of the Second Amended Petition.

B. PLAINTIFF DEVELOPED TARDIVE DYSKINESIA AND ORAL DYSKINESIA AFTER INGESTING REGLAN/METOCLOPRAMIDE

58. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 58 of the Second Amended Petition.

59. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 59 of the Amended Petition.

60. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 60 of the Amended Petition.

61. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 61 of the Amended Petition.

62. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 62 of the Amended Petition.

63. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 63 of the Amended Petition.

64. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 64 of the Amended Petition.

65. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 65 of the Amended Petition.

66. PLIVA states that the risks and side effects of metoclopramide are set forth in the FDA-approved package insert for Reglan. PLIVA denies that paragraph 66 of the Amended Petition completely or accurately characterizes the FDA-approved package insert for metoclopramide. Further, PLIVA denies that paragraph 66 of the Amended Petition completely or accurately characterizes the symptoms of tardive dyskinesia. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 66 of the Amended Petition.

67. PLIVA denies that paragraph 67 of the Amended Petition completely or accurately characterizes the symptoms “dyskinesia.” PLIVA denies the remaining allegations in paragraph 67 of the Amended Petition.

68. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 68 of the Amended Petition.

69. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 69 of the Amended Petition.

70. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 70 of the Amended Petition.

71. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 71 of the Amended Petition.

72. PLIVA denies the allegations in paragraph 72 of the Amended Petition.

73. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 73 of the Amended Petition.

74. PLIVA denies the allegations in paragraph 74 of the Amended Petition.
75. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 75 of the Amended Petition.
76. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 76 of the Amended Petition.
77. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 77 of the Amended Petition.
78. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 78 of the Amended Petition.
79. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 79 of the Amended Petition.
80. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 80 of the Amended Petition.
81. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 81 of the Amended Petition.
82. PLIVA denies the allegations in paragraph 82 of the Amended Petition.
83. PLIVA denies the allegations in paragraph 83 of the Amended Petition.
84. PLIVA states that metoclopramide is approved for the indications set forth in the FDA-approved package insert for Reglan. PLIVA denies that paragraph 84 of the Amended Petition completely or accurately characterizes the FDA-approved package insert for metoclopramide. PLIVA denies the remaining allegations in paragraph 84 of the Amended Petition.

85. PLIVA denies the allegations in paragraph 85 of the Amended Petition directed to it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 85 of the Amended Petition directed to other defendants.

86. PLIVA states that the risks and side effects of metoclopramide are set forth in the FDA-approved package insert for Reglan. PLIVA denies that paragraph 86 of the Amended Petition completely or accurately characterizes the FDA-approved package insert for metoclopramide. PLIVA denies the allegations in paragraph 86 of the Amended Petition directed to it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 86 of the Amended Petition directed to other defendants.

87. PLIVA denies the allegations in paragraph 87 of the Amended Petition directed to it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 87 of the Amended Petition directed to other defendants.

88. PLIVA denies the allegations in paragraph 88 of the Amended Petition.

89. PLIVA admits that on February 26, 2009, the FDA send correspondence to the holders of NDA 17-854, 21-793, and 17-862 and to the holders of ANDA 74-703, 71-402, and 73-680 requiring that a Box Warning be added to labeling for the metoclopramide class of products, addressing the risk of tardive dyskinesia from chronic use, which speaks for itself. PLIVA denies the remaining allegations in paragraph 89 of the Amended Petition.

90. PLIVA admits that the FDA sent correspondence regarding a Risk Evaluation and Mitigation Strategy (“REMS”) and the distribution of a Medication Guide, which speak for themselves. PLIVA denies the remaining allegations in paragraph 90 of the Amended Petition directed to it and joins issue thereon. PLIVA is without knowledge or information sufficient to

form a belief as to the truth of the allegations in paragraph 90 of the Amended Petition directed to other defendants.

91. PLIVA denies the allegations in paragraph 91 of the Amended Petition directed to it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 91 of the Amended Petition directed to other defendants.

92. PLIVA denies the allegations in paragraph 92 of the Amended Petition.

C. DEFENDANTS' WRONGFUL CONDUCT

93. PLIVA denies the allegations in paragraph 93 of the Amended Petition directed to it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 93 of the Amended Petition directed to other defendants.

94. PLIVA denies the allegations in paragraph 94 of the Amended Petition directed to it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 94 of the Amended Petition directed to other defendants.

95. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 95 of the Amended Petition, including footnote 1.

96. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 96 of the Amended Petition.

97. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 97 of the Amended Petition.

98. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 98 of the Amended Petition.

99. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 99 of the Amended Petition.

100. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 100 of the Amended Petition, including footnote 2.

101. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 101 of the Amended Petition.

102. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 102 of the Amended Petition.

103. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 103 of the Amended Petition.

104. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 104 of the Amended Petition.

105. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 105 of the Amended Petition, including footnote 3.

106. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 106 of the Amended Petition.

107. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 107 of the Amended Petition.

108. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 108 of the Amended Petition.

109. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 109 of the Amended Petition.

110. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 110 of the Amended Petition.

111. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 111 of the Amended Petition.

112. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 112 of the Amended Petition.

113. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 113 of the Amended Petition.

114. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 114 of the Amended Petition.

115. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 115 of the Amended Petition.

116. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 116 of the Amended Petition.

117. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 117 of the Amended Petition.

118. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 118 of the Amended Petition.

119. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 119 of the Amended Petition.

120. PLIVA states that the Hatch-Waxman Act and state law regarding pharmaceutical products speak for themselves. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 120 of the Amended Petition.

121. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 121 of the Amended Petition.

122. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 122 of the Amended Petition.

123. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 123 of the Amended Petition.

124. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 124 of the Amended Petition.

125. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 125 of the Amended Petition.

126. PLIVA admits that it submitted two Abbreviated New Drug Applications (“ANDA”) for Metoclopramide Tablets USP, ANDA application number 72-750 for 5 mg. Metoclopramide Tablets USP, and ANDA application number 71-250 for 10 mg. Metoclopramide Tablets USP. PLIVA denies the remaining allegations in paragraph 126 of the Amended Petition directed to it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 126 of the Amended Petition directed to other defendants.

127. PLIVA admits that the ANDA process is governed by applicable provisions of the Code of Federal Regulations (“CFR”), which include provisions dealing with labeling. PLIVA further admits that CFR requires PLIVA and other generic manufacturers of metoclopramide to submit labels for their metoclopramide products identical in all material respects to the reference listed drug (Reglan) label and that it has complied with all applicable CFR sections governing drug labeling. PLIVA denies that paragraph 127 of the Amended Petition otherwise fully and accurately sets for the relevant CFR provisions governing the ANDA process.

128. PLIVA states that the allegation contained in paragraph 128 of the Amended Petition is an asserted conclusion of law to which no response is required. To the extent a response is required, PLIVA denies the allegation.

129. PLIVA states that the allegation contained in paragraph 129 of the Amended Petition is an asserted conclusion of law to which no response is required. To the extent a response is required, PLIVA denies the allegation.

130. PLIVA denies the allegations in paragraph 130 of the Amended Petition directed to it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 130 of the Amended Petition directed to other defendants.

131. PLIVA denies the allegations in paragraph 131 of the Amended Petition directed to it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 131 of the Amended Petition directed to other defendants.

132. PLIVA denies the allegations in paragraph 132 of the Amended Petition directed to it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 132 of the Amended Petition directed to other defendants.

133. PLIVA states that the allegation contained in paragraph 133 of the Amended Petition is an asserted conclusion of law to which no response is required. To the extent a response is required, PLIVA denies the allegation.

134. PLIVA states that the allegation contained in paragraph 134 of the Amended Petition is an asserted conclusion of law to which no response is required. To the extent a response is required, PLIVA denies the allegation.

135. PLIVA denies the allegations in paragraph 135 of the Amended Petition directed to it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 135 of the Amended Petition directed to other defendants.

136. PLIVA denies the allegations in paragraph 136 of the Amended Petition directed to it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 136 of the Amended Petition directed to other defendants.

137. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 137 of the Amended Petition.

138. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 138 of the Amended Petition.

139. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 139 of the Amended Petition.

140. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 140 of the Amended Petition.

141. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 141 of the Amended Petition.

142. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 142 of the Amended Petition, including footnote 4.

143. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 143 of the Amended Petition.

144. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 144 of the Amended Petition, including all sub-parts and footnote 5.

145. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 145 of the Amended Petition, including footnotes 6 and 7.

146. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 146 of the Amended Petition, including footnote 7-9.

147. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 147 of the Amended Petition.

148. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 148 of the Amended Petition.

149. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 149 of the Amended Petition.

150. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 150 of the Amended Petition.

151. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 151 of the Amended Petition.

152. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 152 of the Amended Petition.

153. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 153 of the Amended Petition.

154. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 154 of the Amended Petition.

155. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 155 of the Amended Petition.

156. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 156 of the Amended Petition.

157. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 157 of the Amended Petition.

158. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 158 of the Amended Petition.

159. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 159 of the Amended Petition.

160. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 160 of the Amended Petition.

161. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 161 of the Amended Petition.

162. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 162 of the Amended Petition.

163. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 163 of the Amended Petition.

164. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 164 of the Amended Petition.

165. PLIVA denies the allegations in paragraph 165 of the Amended Petition directed towards it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 165 of the Amended Petition.

166. PLIVA denies the allegations in paragraph 166 of the Amended Petition directed towards it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 166 of the Amended Petition.

167. PLIVA denies the allegations in paragraph 167 of the Amended Petition directed towards it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 167 of the Amended Petition.

168. PLIVA denies the allegations in paragraph 168 of the Amended Petition directed towards it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 168 of the Amended Petition.

169. PLIVA denies the allegations paragraph 169 of the Amended Petition directed towards it, including footnote 169. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 169 of the Amended Petition, including footnote 10.

170. PLIVA denies the allegations paragraph 170 of the Amended Petition directed towards it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 170 of the Amended Petition.

171. PLIVA denies the allegations paragraph 171 of the Amended Petition directed towards it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 171 of the Amended Petition.

172. PLIVA denies the allegations paragraph 172 of the Amended Petition directed towards it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 172 of the Amended Petition.

173. PLIVA denies the allegations paragraph 173 of the Amended Petition directed towards it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 173 of the Amended Petition.

174. PLIVA denies the allegations paragraph 174 of the Amended Petition directed towards it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 174 of the Amended Petition.

175. PLIVA denies the allegations paragraph 175 of the Amended Petition directed towards it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 175 of the Amended Petition.

176. PLIVA denies the allegations paragraph 176 of the Amended Petition directed towards it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 176 of the Amended Petition.

177. PLIVA denies the allegations paragraph 177 of the Amended Petition directed towards it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 177 of the Amended Petition.

178. PLIVA denies the allegations paragraph 178 of the Amended Petition directed towards it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 178 of the Amended Petition.

179. PLIVA denies the allegations in paragraph 179 of the Amended Petition.

COUNT I
NEGLIGENCE, NEGLIGENT MISREPRESENTATION AND NEGLIGENT SUPPLY
OF INFORMATION FOR THE GUIDANCE OF OTHERS
PLAINTIFF V. WYETH, SCHWARZ AND ALAVEN
(BRAND DEFENDANTS)

180. In response to paragraph 180 of the Amended Petition, PLIVA incorporates by reference and restates herein paragraphs 1 through 179 of this Answer.

181-225. PLIVA states that the allegation in footnote 13 is an asserted conclusion of law to which no response is required. To the extent a response is required, PLIVA denies the allegation. The remaining allegations in paragraphs 181 through 225 of the Amended Petition, including all subparts and footnotes 11 and 12, are directed to other defendants and therefore, no response is required by PLIVA. To the extent a response is required, PLIVA lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraphs 181 through 225 of the Amended Petition, including all subparts and footnotes 11 and 12.

COUNT II
NEGLIGENCE
PLAINTIFF V. PLIVA, TEVA USA, and BARR
(GENERIC DEFENDANTS)

226. In response to paragraph 226 of the Amended Petition, PLIVA incorporates by reference and restates herein paragraphs 1 through 225 of this Answer.

227. PLIVA admits that it has engaged in the manufacture and sale of generic metoclopramide. PLIVA denies the remaining allegations in paragraph 227 of the Amended

Petition directed to it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 227 of the Amended Petition directed to other defendants.

228. PLIVA admits that it has engaged in the manufacture and sale of generic metoclopramide. PLIVA denies the remaining allegations in paragraph 228 of the Second Amended Petition directed to it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 228 of the Second Amended Petition directed to other defendants.

229. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 229 of the Amended Petition.

230. PLIVA admits that it submitted two ANDAs for Metoclopramide Tablets USP to the FDA, ANDA application number 72-750 for 5 mg. Metoclopramide Tablets USP, and ANDA application number 71-250 for 10 mg. Metoclopramide Tablets USP. PLIVA denies the remaining allegations in paragraph 230 of the Amended Petition directed to it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 230 of the Amended Petition directed to other defendants.

231. PLIVA admits that the ANDA process is governed by applicable provisions of the CFR, which include provisions dealing with labeling. PLIVA further admits that the CFR requires PLIVA and other generic manufacturers of metoclopramide to submit labels for their metoclopramide products identical in all material respects to the reference listed drug (Reglan) label and that it has complied with all applicable CFR sections governing drug labeling. PLIVA denies that paragraph 231 of the Amended Petition otherwise fully and accurately sets forth the relevant CFR provisions governing the ANDA process.

232. PLIVA states that the allegation contained in paragraph 232 of the Amended Petition is an asserted conclusion of law to which no response is required. To the extent a response is required, PLIVA denies the allegation.

233. PLIVA states that the allegation contained in paragraph 233 of the Amended Petition is an asserted conclusion of law to which no response is required. To the extent a response is required, PLIVA denies the allegation.

234. PLIVA denies the allegations in paragraph 234 of the Amended Petition directed to it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 234 of the Amended Petition directed to other defendants.

235. PLIVA denies the allegations in paragraph 235 of the Amended Petition directed to it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 235 of the Amended Petition directed to other defendants.

236. PLIVA denies the allegations in paragraph 236 of the Amended Petition, including all subparts, directed to it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 236 of the Amended Petition, including all subparts, directed to other defendants.

237. PLIVA denies the allegations in paragraph 237 of the Amended Petition directed to it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 237 of the Amended Petition directed to other defendants.

238. PLIVA denies the allegations in paragraph 238 of the Amended Petition directed to it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 238 of the Amended Petition directed to other defendants.

239. PLIVA denies the allegations in paragraph 239 of the Amended Petition directed to it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 239 of the Amended Petition directed to other defendants.

240. PLIVA denies the allegations in paragraph 240 of the Amended Petition directed to it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 240 of the Amended Petition directed to other defendants.

COUNT III

BREACH OF WARRANTY

PLAINTIFF V. PLIVA, TEVA USA, and BARR

(GENERIC DEFENDANTS)

241. In response to paragraph 241 of the Amended Petition, PLIVA incorporates by reference and restates herein paragraphs 1 through 240 of this Answer.

242. PLIVA denies the allegations in paragraph 242 of the Amended Petition directed to it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 242 of the Amended Petition directed to other defendants.

243. PLIVA denies the allegations in paragraph 243 of the Amended Petition directed to it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 243 of the Amended Petition directed to other defendants.

244. PLIVA denies the allegations in paragraph 244 of the Amended Petition directed to it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 244 of the Amended Petition directed to other defendants.

245. PLIVA denies the allegations in paragraph 245 of the Amended Petition directed to it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 245 of the Amended Petition directed to other defendants.

246. PLIVA denies the allegations in paragraph 246 of the Amended Petition directed to it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 246 of the Amended Petition directed to other defendants.

247. PLIVA denies the allegations in paragraph 247 of the Amended Petition directed to it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 247 of the Amended Petition directed to other defendants.

248. PLIVA denies the allegations in paragraph 248 of the Amended Petition directed to it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 248 of the Amended Petition directed to other defendants.

249. PLIVA denies the allegations in paragraph 249 of the Amended Petition directed to it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 249 of the Amended Petition directed to other defendants.

250. PLIVA denies the allegations in paragraph 250 of the Amended Petition directed to it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 245 of the Amended Petition directed to other defendants.

COUNT IV
MISREPRESENTATION AND FRAUD
PLAINTIFF V. PLIVA, TEVA USA, and BARR
(GENERIC DEFENDANTS)

251. In response to paragraph 251 of the Amended Petition, PLIVA incorporates by reference and restates herein paragraphs 1 through 250 of this Answer.

252. PLIVA denies the allegations in paragraph 252 of the Amended Petition directed to it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 252 of the Amended Petition directed to other defendants.

253. PLIVA denies the allegations in paragraph 253 of the Amended Petition directed to it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 253 of the Amended Petition directed to other defendants.

254. PLIVA denies the allegations in paragraph 254 of the Amended Petition directed to it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 254 of the Amended Petition directed to other defendants.

255. PLIVA denies the allegations in paragraph 255 of the Amended Petition directed to it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 255 of the Amended Petition directed to other defendants.

256. PLIVA denies the allegations in paragraph 256 of the Amended Petition directed to it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 256 of the Amended Petition directed to other defendants.

257. PLIVA denies the allegations in paragraph 257 of the Amended Petition directed to it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 257 of the Amended Petition directed to other defendants.

258. PLIVA denies the allegations in paragraph 258 of the Amended Petition directed to it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 258 of the Amended Petition directed to other defendants.

259. PLIVA denies the allegations in paragraph 259 of the Amended Petition directed to it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 259 of the Amended Petition directed to other defendants.

260. PLIVA denies the allegations in paragraph 260 of the Amended Petition directed to it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 260 of the Amended Petition directed to other defendants.

COUNT V

NEGLIGENCE

PLAINTIFF V. WOLTERS KLUWER HEALTH, INC., WOLTERS KLUWER US, INC.

and FACTS & COMPARISONS (PEM DEFENDANTS)

261. In response to paragraph 261 of the Amended Petition, PLIVA incorporates by reference and restates herein paragraphs 1 through 260 of this Answer.

262-277. The allegations in paragraphs 262 through 277 of the Amended Petition are directed to other defendants and therefore, no response is required by PLIVA. To the extent a response is required, PLIVA lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraphs 262 through 277 of the Amended Petition.

COUNT VI
STRICT PRODUCT LIABILITY
PLAINTIFF V. PLIVA, TEVA USA, and BARR
(GENERIC DEFENDANTS)

278. In response to paragraph 278 of the Amended Petition, PLIVA incorporates by reference and restates herein paragraphs 1 through 277 of this Answer.

279. PLIVA admits that it has engaged in the manufacture, sale and distribution of generic metoclopramide. PLIVA denies the remaining allegations in paragraph 279 of the Amended Petition directed to it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 279 of the Amended Petition directed to other defendants.

280. PLIVA denies the allegations in paragraph 280 of the Amended Petition directed to it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 280 of the Amended Petition directed to other defendants.

281. PLIVA denies the allegations in paragraph 281 of the Amended Petition, including all subparts, directed to it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 281 of the Amended Petition, including all subparts, directed to other defendants.

282. PLIVA denies the allegations in paragraph 282 of the Amended Petition directed to it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 282 of the Amended Petition directed to other defendants.

283. PLIVA denies the allegations in paragraph 283 of the Amended Petition directed to it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 283 of the Amended Petition directed to other defendants.

284. PLIVA denies the allegations in paragraph 284 of the Amended Petition directed to it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 284 of the Amended Petition directed to other defendants.

285. PLIVA denies the allegations in paragraph 285 of the Amended Petition directed to it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 285 of the Amended Petition directed to other defendants.

286. PLIVA denies the allegations in paragraph 286 of the Amended Petition directed to it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 286 of the Amended Petition directed to other defendants.

287. PLIVA denies the allegations in paragraph 287 of the Amended Petition directed to it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 287 of the Amended Petition directed to other defendants.

COUNT VII [VI]¹

VIOLATION OF THE MISSOURI MERCHANDISING PRACTICES ACT

PLAINTIFF V. ALL DEFENDANTS

288. In response to paragraph 288 of the Amended Petition, PLIVA incorporates by reference and restates herein paragraphs 1 through 287 of this Answer.

¹ Plaintiff has incorrectly numbered this Count in non-sequential order. PLIVA, Inc. will respond to plaintiff's Amended Petition referring to the correct sequential Count number and note the mis-numbered Count referenced by plaintiff in brackets following the correct Count number.

289. PLIVA states that the allegation contained in paragraph 289 of the Amended Petition is an asserted conclusion of law to which no response is required. To the extent a response is required, PLIVA denies the allegation.

290. PLIVA denies the allegations in paragraph 290 of the Amended Petition directed to it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 290 of the Amended Petition directed to other defendants.

291. PLIVA denies the allegations in paragraph 291 of the Amended Petition directed to it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 291 of the Amended Petition directed to other defendants.

COUNT VIII

JOINT AND SEVERAL LIABILITY

PLAINTIFF V. ALL DEFENDANTS

292. In response to paragraph 292 of the Amended Petition, PLIVA incorporates by reference and restates herein paragraphs 1 through 291 of this Answer.

293. PLIVA denies the allegations in paragraph 293 of the Amended Petition directed to it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 293 of the Amended Petition directed to other defendants.

COUNT IX

PUNITIVE DAMAGES

PLAINTIFF V. ALL DEFENDANTS

294. In response to paragraph 294 of the Amended Petition, PLIVA incorporates by reference and restates herein paragraphs 1 through 293 of this Answer.

295. PLIVA denies the allegations in paragraph 295 of the Amended Petition directed to it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 295 of the Amended Petition directed to other defendants.

COUNT X

PLAINTIFF'S DAMAGES

PLAINTIFF V. ALL DEFENDANTS

296. In response to paragraph 296 of the Amended Petition, PLIVA incorporates by reference and restates herein paragraphs 1 through 295 of this Answer.

297. PLIVA denies the allegations in paragraph 297 of the Amended Petition, including all subparts, directed to it. PLIVA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 297 of the Amended Petition, including all subparts, directed to other defendants.

PLIVA admits that plaintiff seeks the relief requested in sections (a) through (e) of the section beginning with "WHEREFORE", but denies that plaintiff is entitled to the relief, or any recovery whatsoever.

DEFENSES

1. The Amended Petition fails to state a claim upon which relief can be granted.
2. Plaintiff's claims should be dismissed or transferred due to improper and/or inconvenient venue.
3. Plaintiff has failed to join all necessary and appropriate parties.
4. PLIVA is not a proper party-defendant.
5. Any claim or cause of action that plaintiff may have had is barred by the applicable statutes of limitation and/or statutes of repose.

6. This Court has no in personam jurisdiction over PLIVA.
7. This Court has no subject matter jurisdiction over this action.
8. Plaintiff's claims are barred by the doctrine of unclean hands, laches, waiver and/or estoppel.
9. Any metoclopramide product at issue in this litigation has been formulated, designed, tested, manufactured, processed, distributed, and labeled in accordance with the provisions of the federal Food, Drug and Cosmetic Act and any regulations promulgated thereunder. Therefore, plaintiff's claims are barred or preempted by federal law pursuant to the Supremacy Clause of the United States Constitution, Article VI, Clause 2, and the laws of the United States.
10. Any metoclopramide product that left PLIVA'S control complied with applicable codes, standards, regulations, and specifications established, adopted, promulgated, or approved by the United States or by applicable state law, or by any agency of the United States or applicable state. The metoclopramide product was reasonably fit, suitable, and safe for its intended purpose.
11. Any metoclopramide product described in the Second Amended Petition was modified, altered, or changed from the condition in which it was sold, which modification, alteration, or change caused or contributed to cause plaintiff's alleged damages.
12. Any metoclopramide product that is the subject of this litigation conformed precisely in all ways to its specifications and performance standards and posed no danger in its manufacture and composition.
13. At the time any metoclopramide product left PLIVA's control, a practical and technically feasible alternative design or formulation was not available that would have

prevented the harm for which plaintiff seeks to recover damages without substantially impairing the reasonably anticipated or intended function of the product. Further, all reasonable precautions consistent with legal duties and obligations were taken to protect third parties from any dangers posed by the inherent characteristics of the product.

14. The benefits of metoclopramide outweigh the risk of danger or harm, if any, inherent in the product.

15. There is no duty to warn about any possible dangers that were not known at the time of manufacture and sale of any metoclopramide product in question.

16. Any communications and/or actions between any of the defendants and the United States Food and Drug Administration and/or any governmental agency or entity are constitutionally protected under the Noerr-Pennington Doctrine and the First Amendment to the United States Constitution.

17. At all times relevant herein, if any products were purchased from PLIVA, those products were sold in a reasonable and prudent manner based upon available medical and scientific knowledge and further were processed in accordance with and pursuant to all applicable regulations of the federal Food and Drug Administration.

18. Based on the state of scientific, medical, and technological knowledge at the time they were marketed, the pharmaceuticals identified in the Second Amended Petition were reasonably safe for their normal and foreseeable uses. In light of the existing reasonably available medical, scientific, and technological knowledge, the design characteristics, if any, that allegedly caused the damages of which plaintiff complains, or the alleged risk of such characteristics, could not have been known. PLIVA's actions conformed to the state of the art of reasonably available scientific and technological knowledge at all times relevant to this lawsuit.

19. PLIVA at all times discharged its duty to warn through appropriate and adequate warnings in accordance with federal statutes and regulations consistent with the existing state of medical and scientific knowledge.

20. The advertisements, if any, with respect to the pharmaceuticals at issue were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States and applicable state constitutions.

21. If plaintiff sustained damages by reason of the matters alleged in the Second Amended Petition, which is denied, then said damages were caused solely by or contributed to by the acts or fault of third parties and were not caused or contributed to by any acts or fault of PLIVA, its officers, agents, contractors, servants, employees, or others for whom it was responsible.

22. Plaintiff's damages, if any, were proximately caused by unforeseeable, independent, intervening, or superseding events beyond the control, and unrelated to the conduct of PLIVA. The actions and omissions of PLIVA, if any, were superseded by such unforeseeable, independent, intervening, and superseding events.

23. The injuries and damages claimed by plaintiff resulted from her own conduct so that plaintiff's claims are barred, in whole or in part, by the comparative negligence, fault, or responsibility attributed to plaintiffs. Thus, plaintiffs' claims should be dismissed, reduced, offset, or barred in accordance with the principles of contributory negligence and/or comparative negligence. Plaintiff's recovery of damages, if any exist, must be reduced by the comparative negligence and/or fault of plaintiff and other persons, including responsible non-parties, pursuant to applicable state law.

24. The injuries and damages claimed by plaintiff were caused, in whole or in part, by the acts or omissions of persons other than PLIVA over whom PLIVA had no control. Therefore, any recovery by plaintiff should be apportioned in direct proportion to such fault in accordance with applicable law.

25. Any injuries or damages sustained by plaintiff were directly and proximately caused by the failure of plaintiff to heed warnings and instructions. Therefore, no recovery is available to plaintiff.

26. If plaintiff sustained damages as alleged in the Amended Petition, which is denied, plaintiff failed to mitigate her damages.

27. Plaintiff's misuse of the product, which was not reasonably foreseeable, caused plaintiff's alleged damages, if any, and plaintiff's claims therefore may be barred or reduced by applicable law.

28. Plaintiff's claims are barred to the extent the injuries alleged in the Amended Petition were caused or enhanced by pre-existing or unrelated medical, genetic, environmental, or psychiatric conditions, diseases or illnesses, by plaintiff's own idiosyncratic reactions to the product(s), and/or by operation of nature.

29. Plaintiff's claims are barred on the grounds that plaintiff knew, or in the exercise of ordinary care should have known, of the risks of the injuries or damages alleged in the Amended Petition, if any, and nevertheless, did freely and voluntarily assume said risks, and in this undertaking proximately caused and contributed to the losses, injuries, or damage, if any, alleged by plaintiff.

30. Plaintiff's claims may be barred or reduced by applicable state product liability law.

31. Plaintiff assumed all risks attendant with the use of the product(s) in a manner other than directed.

32. Plaintiff's claims against PLIVA are barred by the learned intermediary doctrine.

33. There is no responsibility for either the acts or omissions of the knowledgeable users or misinformation or lack of information provided to plaintiff by others.

34. With respect to each and every cause of action, plaintiff is not entitled to recover because of the delay and the fundamental unfairness and prejudice due to the excessive delay from the date of the alleged use of the products allegedly sold by PLIVA and the filing of the Amended Petition.

35. Plaintiff is barred, in whole or in part, from recovery due to spoliation of evidence.

36. Plaintiff's claims are barred, in whole or in part, by the laws of other jurisdictions.

37. Plaintiff failed to give notice of any alleged breach of any warranty within a reasonable time after plaintiff discovered or should have discovered any such alleged breach of warranty and are, therefore, barred from any recovery for such claims.

38. There were no warranties, either express or implied, between plaintiff and PLIVA and/or plaintiff is barred from asserting causes of action arising from any such alleged warranties because plaintiff is not in privity with PLIVA.

39. PLIVA breached no warranties, either express or implied, which may have existed between it and plaintiff.

40. The express and implied warranties alleged to have been made were expressly disclaimed and excluded by the package insert; any and all statement made concerning the product applied only when used as directed.

41. The Amended Petition fails to allege facts sufficient to entitle plaintiff to an award of exemplary or punitive damages.

42. Plaintiff's claims for exemplary and punitive damages are prohibited under the Fifth, Sixth, Eighth, and Fourteenth Amendments of the United States Constitution and/or applicable state constitutions.

43. Plaintiff may be prohibited from including any claim for punitive damages in the Amended Petition pursuant to applicable state law regarding exemplary damages.

44. To the extent that the claims stated in the Amended Petition have been settled, compromised, or otherwise discharged, a set off is due.

45. Plaintiff failed to state a claim upon which attorneys' fees can be awarded.

46. PLIVA adopts and relies upon all provisions and defenses afforded it under Restatement of Torts 2d, § 402A, including the comments thereto.

47. PLIVA reserves the right to raise all defenses provided in sections 2, 4, and 6 of the Restatement (Third) of Torts: Product Liability, if the Court finds that it is applicable in this case.

48. PLIVA incorporates all those defenses available under the applicable state law.

49. Plaintiff has failed to obtain sufficient service.

50. Plaintiff's claims may be barred or reduced by applicable state law.

51. Plaintiff's claims for exemplary damages are limited or barred by applicable state law.

52. Plaintiff's claims, if any, are barred, reduced and/or limited pursuant to any other applicable limitations of awards, caps on recovery, and setoffs permitted by law, including, but

not limited to applicable state law regarding noneconomic loss or injury, and applicable state law related to amounts paid or provided by collateral sources.

53. PLIVA adopts and relies upon all provisions and defenses afforded it under the United States Constitution and any applicable state constitution.

54. To the extent plaintiff's claims are based on alleged misrepresentations or omissions made to the FDA, such claims are barred pursuant to applicable law.

55. Upon information and belief, plaintiff's Amended Petition and each cause of action therein, is barred because PLIVA did not owe any duty to plaintiff.

56. Plaintiff's Amended Petition fails to state a cause of action against PLIVA because plaintiff does not allege that PLIVA manufactured, distributed, or sold a product that allegedly caused plaintiff's injuries and damages. If plaintiff's claims are sustained, they would violate PLIVA's right to procedural and substantive due process and to equal protection under the Fourteenth Amendment of the United States Constitution and the Constitution of the applicable state.

57. PLIVA did not proximately cause plaintiff's alleged injuries, if any.

58. PLIVA invokes the provisions of any applicable state code, statute, or law regarding apportionment of fault.

59. Applicable state law precludes any out-of-state plaintiff from maintaining a cause of action in this forum that they could not otherwise bring in their state of residence.

60. Plaintiff failed to give notice as required by provisions of applicable state law.

61. Plaintiff's common law claims and/or breach of warranty claims are preempted and/or superseded by applicable state statutory law.

62. The allegations in plaintiff's Amended Petition relating to articles, studies, reports, textbooks, editorials, actions of the FDA, reports to the FDA, hearings, and letters are immaterial, impertinent and should be stricken.

63. With respect to each and every purported cause of action, the acts of PLIVA were, at all time, done in good faith and without malice.

64. Plaintiff's claims are barred by additional defenses that may arise during the course of this litigation, which PLIVA reserves the right to assert.

65. PLIVA incorporates the defenses of all others who are or may become parties to this action as though more fully set forth herein.

66. PLIVA reserves the right to amend its answer to add any additional affirmative defenses or other defenses as additional information is obtained.

WHEREFORE, having fully answered, PLIVA, Inc., respectfully prays for the following relief:

1. That judgment be entered in its favor, dismissing plaintiff's Amended Petition in its entirety with prejudice.

2. That judgment be entered in its favor for costs, expenses, and reasonable attorneys' fees incurred in connection with this matter; and

3. That this Court grant it such other and further relief, both at law and in equity, whether general or special, to which it may be justly entitled.

JURY DEMAND

PLIVA, Inc., hereby demands a trial by jury.

Respectfully submitted this 2nd day of March, 2011.

STINSON MORRISON HECKER LLP

By: /s/ Sandra J. Wunderlich

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Attorneys for Defendant PLIVA, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on this 2nd day of March, 2011, the foregoing instrument was electronically filed with the Clerk of the Court and served upon all counsel of record via the Court's CM/ECF system.

/s/ Sandra J. Wunderlich
Attorney for Defendant PLIVA, Inc.